

AUG 27 1998

K 980831

SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

1. General Information

Classification:	Class II Magnetic Resonance (MR) Diagnostic Device
Common/Usual Name:	Magnetic Resonance (MR) Device Option
Proprietary Name:	Image Post-Processing Techniques
Establishment Registration:	Picker International, Inc. World Headquarters 595 Miner Road Highland Heights, Ohio 44143 FDA Owner Number: #1580240 FDA Registration Number: #1525965
Performance Standards:	No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

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FDA/CDRH/ODE/DAC

2. Intended Uses

The intended use and indications for use for each of the types of Post-Processing Techniques described in this submission are described below.

ProPak Techniques

The ProPak Package for Picker MR systems or workstations provide supplemental information regarding contrast changes over time for those images extracted from MR temporal datasets. The indications for use for the MR system remain unchanged.

Apparent Diffusion Coefficient (ADC) Mapping

This submission adds the following sentence to the indications for use statement for Picker's Diffusion-Weighted MR Imaging Package.

Post-processing using ADC mapping produces parametric images with further contrast manipulation.

3. Device Description

There are two basic types of post-processing techniques included in this submission. The first type is known as ProPak and is a set of techniques for processing temporally resolved image data sets and performing general perfusion analysis. The second type of technique is called ADC mapping and is for processing data from diffusion-weighted imaging sequences. All of the techniques included in this submission are for processing existing images that have already been reconstructed.

4. Safety and Effectiveness

The Post-Processing Techniques described in this submission are substantially equivalent in technological characteristics and intended use to the GE Functool Option, the Philips Quantitative Analysis Package and the Picker Diffusion-Weighted Imaging Package. The following table has been compiled in order to demonstrate this substantial equivalence.

SUBSTANTIAL EQUIVALENCE CHART

Parameter	Image Post-Processing Techniques	Predicate Devices GE FuncTool Option (K960265), Philips Quantitative Anal. (K971965), Diffusion Imaging (K974530),
Compatibility	Same.	Available on Independent Workstations or the MR System Operator's Console (See K960265)
Inputs	<ul style="list-style-type: none"> • MR images • Single or multi-slice datasets with equally spaced time intervals (ProPak) • Diffusion-weighted images (ADC Mapping) 	<ul style="list-style-type: none"> • CT and MR images • Single or multi-slice datasets with equally spaced time intervals (See K960265)
Features	<ul style="list-style-type: none"> • Semi-automated • Color parametric images (optional) • Analysis on a pixel-by-pixel basis or region of interest • Time intensity information in plot or tabular form 	<ul style="list-style-type: none"> • Automated • Color parametric images • Overlay of parametric images on to anatomical reference images • Analysis on a pixel-by-pixel basis or region of interest • Time intensity information in plot or tabular form (See K960265 and K971965)

Parameter	Image Post-Processing Techniques	Predicate Devices GE FuncTool Option (K960265), Philips Quantitative Anal. (K971965), Diffusion Imaging (K974530),
Filming and Archiving	Same.	Images can be filmed, stored in image database or archived with rest of patient exam. (See K960265)
Anatomy of Interest	Same.	Brain and Body Imaging (See K960265)
Processing Algorithms	<ul style="list-style-type: none"> • Area Mapping • Time to Peak Mapping • ADC Mapping 	<ul style="list-style-type: none"> • Negative Enhancement Integral • Mean Time to Enhance (See K960265)
Indications for Use	<p><u>ProPak Techniques</u> The ProPak Package for Picker MR systems or workstations provide supplemental information regarding contrast changes over time for those images extracted from MR temporal datasets. The indications for use for the MR system remain unchanged.</p>	<p><u>FuncTools (K960265)</u> The FuncTool option to the Advantages Windows workstation is a software module that provides supplemental information to those images extracted from CT and MR temporal datasets.</p> <p><u>Quantitative Analysis (K971965)</u> The CT/MR Quantitative Analysis Package is intended for use where visualization and analysis of CT and MR dynamic studies, showing changes in contrast over time, are useful or necessary.</p>

Parameter	Image Post-Processing Techniques	Predicate Devices GE FuncTool Option (K960265), Philips Quantitative Anal. (K971965), Diffusion Imaging (K974530),
Indications for Use (cont.)	<p><u>ADC Mapping</u> Same as Diffusion Imaging with the addition of the following sentence: Post-processing using ADC mapping produces parametric images with further contrast manipulation.</p>	<p><u>Diffusion Imaging (K974530)</u> The Picker Diffusion-Weighted MR Imaging Package has been designed to image the diffusive mobility of water or other proton-containing molecules. One important clinical application is to visualize the apparent loss of mobility of water molecules in brain tissue affected by acute stroke. Areas of decreased diffusion, as is observed in acute cerebral infarcts, appear as areas of higher image intensity. Diffusion weighted MR pulse sequences are more accurate than conventional MRI pulse sequences in identifying the occurrence of acute stroke during the first 24 hours after onset of symptoms.</p>



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1998

Elaine K. Keeler, Ph.D.
Manager, Clinical Science
Picker International, Inc.
595 Miner Road
Cleveland, OH 44143

Re: K980831
Image Post-Processing Techniques
(ProPak and Apparent Diffusion Coefficient Mapping)
Dated: June 8, 1998
Received: June 9, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Keeler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980831

Device Name: Image Post-Processing Techniques

Indications for Use:

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Diffusion weighted MR pulse sequences are more accurate than conventional MRI pulse sequences in identifying the occurrence of acute stroke during the first 24 hours after onset of symptoms.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David M. Bejerman

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K980831

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)